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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,135

06/08/2006

Dan Hashimshony

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08/05/2010

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EXAMINER

DANEGA, RENEE A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,135	Applicant(s) HASHIMSHONY ET AL.	
	Examiner Renee Danega	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 13, 14, 36, and 37 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claims 1 and 24 as written require the structure to have 6 faces. Dependent claims limit this structure to a sac-like or stocking structure. It is unclear to the examiner based on the Figures and written disclosure of the sac-like and stocking structures how they could have six faces.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8, 15-16, 18-21, 23-27, 29-32, 39-40, 42-45, and 47-48, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle (WO 02/059571)

- Regarding claims 1 and 24, Nagle teaches a device and method for tissue handling comprising providing a device comprising a structure configured

for receiving and holding a tissue specimen wherein the specimen can include tissue positional references; and at least one holder (202) for holding the first outline frame (204) with the tissue specimen thus fixing the orientation (226) of the tissue specimen in a manner allowing a clear approach for manipulation of the specimen (spaces between finger-like members); and device positional references (38) for fixing the orientation of the tissue specimen when held by the device (Figures 12-15). Nagle doesn't expressly teach the specimen having tissue positional references in this embodiment. However, Nagle teaches another embodiment in which points of interest (36) are marked in the tissue (Figure 2) and these positional references are aligned with the container (Figure 1) in order to keep track of the tissue point of interest (36) during handling (abstract) (Figure 1-2). It would have been obvious in view of Nagle to provide specimen markers and align them with container markers in the first embodiment of Nagle in order to keep track of particular points of interest in the sample during handling.

- Regarding claims 2 and 26, Nagle teaches the device configured to define tissue lateral and superior sides and a top face (208, 210, 212) (Figure 12).
- Regarding claim 3 and 27, Nagle teaches the device substantially transparent to at least one imaging modality selected from the group

consisting of x-ray imaging, gamma imaging, and MRI (page 18, line 20-
page 19, line 8).

- Regarding claim 4 and 28, Nagle teaches a device capable of receiving tissue prior to its complete removal due to its open configuration (Figure 13).
- Regarding claim 5 and 21, Nagle doesn't expressly teach the device positional references are positional references built into the structure of the device in this embodiment. However, Nagle teaches device positional references in other embodiments in order to use the container as a measurement tool (32) (Figure 1). It would have been obvious in view of other embodiments of Nagle to provide device positional references on the outside of all the embodiments in order to use the container to measure the specimen.
- Regarding claims 6 and 30, Watkins doesn't expressly teach device positional reference to be based on color code. However, Nagle teaches the device positional references to include a color code of using different colored ink (column 3, lines 10-17) (column 5, lines 35-40). It would have been obvious in view of Nagle to use color coding in Watkins in order to provide orientation inspection from quick visual inspection.
- Regarding claims 7 and 31, Nagle teaches the device positional references based on sutures of different lengths in order to code for sides such as the superior and lateral extremes of the specimen (page 10, lines

3-12). It would have been obvious in view of Nagle to incorporate sutures of different lengths in the device of Watkins in order to identify the orientation of the specimen within the device.

- Regarding claims 8 and 32, Nagle teaches the device is formed as a rigid body (pg 18, lines 18-20).
- Regarding claims 15 and 39, Nagle teaches the device formed as a box outline comprising a box outline body (204), lid, (202) and at least one holder (fastening member) (Figure 12) (page 20, lines 1-10).
- Regarding claims 16 and 40, Nagle teaches the structure comprising first (202) and second (204) frames designed to be superimposed and receive and hold the tissue (206) there between and at least one holder (fastening member) for holding first and second frames together thus fixing the orientation of the specimen (Figure 12) (page 20, lines 1-10).
- Regarding claims 18, 42, 47, and 50, Nagle teaches the device further including a lining (226) (Figure 14) (page 21, lines 5-12).
- Regarding claims 19, 43, 48, and 51, Nagle doesn't expressly teach the specimen having a grid in this embodiment. However, Nagle teaches another embodiment in which points of interest (36) are marked in the tissue (Figure 2) and these positional references are aligned with the container grid (32) (Figure 1) in order to keep track of the tissue point of interest (36) during handling (abstract) (Figure 1-2). It would have been obvious in view of Nagle to provide grid container markers in the first

embodiment of Nagle in order to keep track of particular points of interest in the sample during handling.

- Regarding claims 20, 21, 44, and 45 Nagle teaches applying a force (page 11, lines 4-10) but doesn't specifically teach the force to be less than 500 grams and between 20 and 200 grams. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a force of 20-200 grams to conform the tissue to the reference device and not unnecessarily distort it, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.
- Regarding claim 23, Nagle teaches the device provided in a plurality of sizes (page 20, lines 10-22).
- Regarding claim 25, Nagle teaches maintaining the specimen immobile in the device (page 21, lines 5-12).

4. Claims 9-11, 14, 32-35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 1 and 24 above, and further in view of Watkins (US 5568534).

- Regarding claims 9-11, 14, 33-35, and 38 Nagle doesn't expressly teach the device to form a flexible or stretchable body. However, Watkins teaches the device to be appropriately rigid, flexible, stretch or expansible and the top to be a resilient cage structure (22) (abstract) (column 3, lines

17-20) (Figure 4). It would have been obvious to one of ordinary skill in view of Watkins to provide flexibility and resilience in the device of Nagle to prevent damaging forces being exerted on the tissue by the device.

5. Claims 12, 13, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 1 and 24 above, and further in view of Heaven et al. (US 5524633) .

- Regarding claims 12 and 36, Nagle doesn't teach the device being a sac-like mesh. However, Heaven teaches a device for tissue handling with a stretchable body and sac-like mesh layer for excising tissue from within the body (abstract). It would have been obvious in view of Heaven to provide stretchable or sac-like mesh in the device of Nagle in order to manipulate it in the body for tissue collection in vivo and not have to transfer it to a new storage device for viewing.
- Regarding claims 13 and 37, Nagle doesn't teach the device to be a stretchable stocking. However, Heaven teaches a device for tissue handling with a stretchable body and stocking configuration for in vivo tissue handling (Figure 12) (abstract). It would have been obvious in view of Heaven to provide a stocking configuration in Nagle for in vivo manipulation of tissue.

6. Claims 17, 41, 46, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claims 15, 16, 24, and 40 above, and further in view of Douglas (US 3743084).

- Regarding claims 17, 41, 46, and 49, Nagle teaches the holder to be a fastening member but not a surgical latex band. However, Douglas teaches a package held together with a spring or a rubber band to be an obvious substitution (column 1, lines 64-68). Furthermore banding items together is a common coupling mechanism. It would have been obvious in view of Douglas to provide a holder to be a latex band in Nagle's device.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagle as applied to claim 1 above, and further in view of Garrigus (US 4837795).

- Regarding claim 22, Nagle doesn't teach handles on the device. However, Garrigus teaches a tissue handling device with handles (31) (Figure 1). It would have been obvious in view of Garrigus to provide handles on the device of Nagle in order more easily move and grab the device.

Response to Arguments

8. Applicant's arguments, filed 5/31/10, with respect to the rejection(s) of the claim(s) under Nagle and Watkins have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Nagle PCT.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736